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K040740

1/3

11 510(k) SUMMARY

11.0 510(k) Summary

Coapt Systems is providing a summary of the safety and effectiveness information available for the ENDOTINE TransBleph™ Device. This 510(k) summary of safety and effectiveness information is submitted in accordance with the requirements of 21 CFR §807.92 and pursuant to Section 12, Part (a)(i)(3A) of the Safe Medical Devices Act of 1990.

SPONSOR/APPLICANT NAME AND ADDRESS

Coapt Systems, Inc.
1820 Embarcadero Road
Palo Alto, CA
Telephone: (650) 461-7600
Facsimile: (650) 213-9336

CONTACT INFORMATION

Lori DonDiego
Director, Regulatory Affairs
Coapt Systems, Inc.
1820 Embarcadero Road
Palo Alto, CA
Telephone: (650) 461-7647
Facsimile: (650) 213-9336
Email: ldondiego@coaptsystems.com

DATE OF PREPARATION OF 510(K) SUMMARY

March 15, 2003

DEVICE TRADE OR PROPRIETARY NAME

ENDOTINE TransBleph™ Device

DEVICE COMMON OR CLASSIFICATION NAME

Classification Name:	Smooth or threaded metallic bone fixation fastener
Regulation Number:	888.3040
Class:	II
Product Code:	HWC

2/3

IDENTIFICATION OF THE LEGALLY MARKETED DEVICES TO WHICH EQUIVALENCE IS BEING CLAIMED

Name of Predicate Device	Name of Manufacturer	510(k) or PMA Number
ENDOTINE Forehead™ Device	Coapt Systems, Inc.	K014153/K023992
Lactosorb® Panels	Walter Lorenz Surgical	K974309
ENDOTINE Chin™ 3.5 Device	Coapt Systems, Inc.	K033524

DEVICE DESCRIPTION

The ENDOTINE TransBleph™ Device kit consists of the brow implant with insertion tool and a drill bit. The TransBleph device along with its insertion tool and drill bit are supplied sterile for single use only.

INTENDED USE STATEMENT

The ENDOTINE TransBleph™ is intended for use in subperiosteal browplasty surgery. The ENDOTINE TransBleph™ is specifically indicated for use to fixate the subdermis to the frontal bone.

SUBSTANTIAL EQUIVLANCE COMPARISON

1. Indications Summary

The ENDOTINE Forehead™ Device intended use statement is nearly identical to the new ENDOTINE TransBleph Device intended use. Both ENDOTINE devices (Forehead and TransBleph) are intended to elevate and fixate soft tissue in facial browlift surgeries. Moreover, the anchoring methods are very similar for both devices, applying a pulling force to the skeletal system for support. Both devices are intended for soft tissue suspension using the patented multi-point technology developed by Coapt Systems.

The similar anatomical sites for use between the ENDOTINE TransBleph™ and ENDOTINE Forehead™ Device suggest no new issues of safety and effectiveness that could affect the substantial equivalence determination.

2. Technological Characteristics Summary

The ENDOTINE TRansBleph™ is substantially equivalent in design, materials and fundamental scientific technology to the ENDOTINE Forehead, Lactosorb Panel and ENDOTINE Chin predicate devices. The technological characteristics of the ENDOTINE TransBleph are similar to many absorbable, implantable general, orthopedic

and plastic surgery devices legally distributed by device manufacturers. Any differences between the ENDOTINE TransBleph™ and the predicate devices are inconsequential and do not raise new issues regarding safety or effectiveness. This statement is substantiated by the mechanical performance data for TransBleph, clinical history to date for the ENDOTINE Forehead/Chin Device and an established safety profile of the device material in both the forehead and other craniofacial sites.

3. Performance Summary

The ENDOTINE TransBleph™ Device is safe and appropriate for the intended use due to the following:

- Its similarity to the predicate device, the ENDOTINE Forehead Device.
- Design performance studies that included cadaveric evaluation, and strength and compression testing results that exceeded specifications.
- Feedback and user observation from several leading surgeons.

The ENDOTINE TransBleph™ performance data meet the applicable standards and fulfill the device requirements as defined in the design specifications.

An appropriate and complete testing program supports the ENDOTINE TransBleph™ is suitable to perform and operate as clinically intended.

SUBSTANTIAL EQUIVALENCE CONCLUSION

Based on the design, materials, function, intended use, and performance evaluations discussed herein, Coapt Systems believes the ENDOTINE TransBleph™ Device is substantially equivalent to the selected predicate devices currently marketed under the Federal Food, Drug and Cosmetic Act. No new issues of safety or effectiveness were raised for the ENDOTINE TransBleph™ Device. Therefore, safety and effectiveness are reasonably assured, justifying 510(k) clearance for commercial sale.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY 1 0 2004

Ms. Lori DonDiego
Director, Regulatory Affairs
Coapt Systems, Inc.
1820 Embarcadero Road
Palo Alto, California 94303

Re: K040740
Trade/Device Name: ENDOTINE TransBleph™ Device
Regulation Number: 21 CFR 888.3040
Regulation Name: Smooth or threaded metallic bone fixation fastener
Regulatory Class: II
Product Code: HWC
Dated: March 19, 2004
Received: March 22, 2004

Dear Ms. DonDiego:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4659. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Miriam C. Provost

for Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

K040740

4 STATEMENT OF INDICATIONS FOR USE

510(k) Number: K 040740 (not yet assigned)

Device Name: ENDOTINE TransBleph™ Device

Indications for Use: The ENDOTINE TransBleph™ Device is intended for use in subperiosteal browplasty fixation. The ENDOTINE TransBleph™ is specifically indicated for use to fixate the sub-dermis to the frontal bone.

Prescription Use ___X___ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Miriam C Provost

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

510(k) Number K040740